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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,262	FETTERMAN ET AL.	
	Examiner	Art Unit	
	GREG POLLOCK	3695	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to claims filed 04/08/2010 and Applicant's request for reconsideration of application 10/722262 filed 04/08/2010.

   The amendment contains original claims 2-4, 6, 12, 16-20, 22-28, 31, 32, and 34-42.

   The amendment contains previously presented claims 5, 11, 15, 21, and 33.

   The amendment contains amended claims 1, 7-10, 13, 14, 29, and 53.

   Claims 43-52 and 54-57 have been canceled.

   As such, claims 1–42 and 53 have been examined with this office action.

Abstract

2. The abstract of the disclosure is objected to because of the use of self-evident clauses. The third sentence of the Abstract reads "In addition, the present invention includes a method". The abstract should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," and in this case "The subject invention". Correction is required. See MPEP § 608.01(b).

3. The abstract first line of the disclosure reads "A method for identifying and assessing risks associated with a pharmaceutical product".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The term "similar" in **claim 9** is a relative term which renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. The phrase "less experienced" in **claim 24** is a relative phrase which renders the claim indefinite. The phrase ""less experienced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. The phrase "high hazard score" in **claim 24** is a relative phrase which renders the claim indefinite. The phrase ""high hazard score" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

8. **Claims 1-42** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the structural elements responsible for performing action within each of the method limits. Claims 2-15 list method steps but do not recite what structural components perform each of the method steps. For example, claim 1

recites inter alia the claim limit "wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient". The structural apparatus performing the action in the claims (diagnosing, prescribing, dispensing, and administering) is not identified, Additionally, it is unclear how the identified claim limits could be amended to perform such tasks. As another example, claim 2 recites the claim limitation implementing said risk management program.". There is no recitation of what structural component is performing this claim limit. Claim 1 recites *inter alia* the claim limit of "designing a risk management intervention program", but does not indicate what structural apparatus performs the claim limit. As another example, claim 4 recites inter alia the claim limit "measuring the effectiveness of said risk management program comprises: measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting ".There is no recitation of what structural component is performing this claim limit. Where it is unclear what is performing a claim limit, the claim limit is broadly interpreted as any means by which the claim limit can be performed, including human means. Similarly, claim limits are recited throughout claims 2-42. To correct this deficiency, it must be clear which disclosed component is performing each and every method step. Further, if the method step is performed by software, it must be made clear that the software resides on a physical media and when read by a

processor executes the method steps (all of which requires support in the specification).

9. **Claim 20** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the claim limit "tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff". The phrase "but not limited to" renders the claim indefinite since the boundary of the claims are "not limited to" the recited limits.

10. **Claim 53** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53 is not sufficiently precise due to the combining of two different statutory classes of invention in a single claim. The preamble of the claim refers to a system, but the body of the claim discusses the specifics of a method step (as evident by such action words as identifying, determining, quantifying, conducting, and designing). A claim is considered indefinite if it does not apprise those skilled in the art of its scope. Amgen, Inc. v. Chugai Pharm. Co., 927 F. 2d 1200, 1217 (Fed. Cir. 1991). A claim is considered indefinite if it does not apprise those skilled in the art of its scope. Amgen, Inc. v. Chugai Pharm. Co., 927 F. 2d 1200, 1217 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. 35 U.S.C. §101 requires that in order to be patentable the invention must be a "new and useful process, machine, manufacture or composition of matter or new and useful improvement thereof" (emphasis added). Applicant **claims 53** is intended to embrace or overlap two different statutory classes of invention as set forth in 35 U.S.C. §101. The preamble of claim 53 refers to a system, but the body of the claim discusses the specifics of a method step (as evident by such action words as identifying, determining, quantifying, conducting, and designing). (see rejection of claims under 35 U.S.C. §112, second paragraph, for specific details regarding this issue)." a claim of this type is precluded by express language of 35 U.S.C. §101 which is drafted so as to set forth statutory the statutory classes of invention in the alternative only", Ex parte Lyell (17USPQ2d 1548).

Claim Interpretation – Method Steps

13. **Claims 1-42** contain claims which do not positively recite the statutory class (thing or product) to which it is tied, by identifying the apparatus that accomplishes the method steps. For example, claim 2 recites the claim limitation implementing said risk management program.". There is no recitation of what

structural component is performing this claim limit. Claim 1 recites *inter alia* the claim limit of "designing a risk management intervention program", but does not indicate what structural apparatus performs the claim limit. As another example, claim 4 recites inter alia the claim limit "measuring the effectiveness of said risk management program comprises: measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting ". Where it is unclear what is performing a method step, such method step it is broadly interpreted to encompass all means by which the claim limit can be performed (including a purely mental step performed by a human). If a claim limit is intended to be interpreted as being performed by a specific structural element, it must be made clear what underlying apparatus is used to perform each recited method step. Merely stating the underlying apparatus in the preamble is not sufficient. Further, if the method step is performed by software, it must be made clear that the software resides on a physical media and when read by a processor executes the method steps (all of which requires support in the specification). It is recommended that the claim be amended to clarify which method steps are performed by automatically by code and which required human decisions or action. **Claims 2-42** all contain claim limits with similar interpretations.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-14, 16, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnard (U.S. Patent No. 5586252) in view of Klass. (U.S. Patent No. 6993402) in further view of Ghouri (PGPub No. 20040049506).

As per claim 1, Barnard teaches a **computer-implemented method for assessing and managing risks associated with utilizing a pharmaceutical product** (risk prioritization [column 2, lines 55-65] of a process failure mode and effects analysis (FMEA) [column 1, line s13-33] Note that the phrase "for assessing and managing risks associated with utilizing a pharmaceutical product" is a statement of intended use and not a positive recitation.) **comprising: identifying, characterizing and ranking, by a processing device, one or more events** (see at least [Figure 11] and related text);
based on the determination, identifying potential failure modes (see at least [Figure 3, element 240] and related text and [column 1, lines 13-20])
automatically quantifying, by the processing device, the potential effect of said failure mode (see at least [Figure 4(c)] [column 6, lines 8-36])
automatically conducting, by the processing device, a hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes (see at least [Figures 8(a)-(c), 9, and 13] and related text. Note that the phrase "to evaluate the need to mitigate the effect of said failure modes" is a statement of intended use and not a positive recitation of a claim limitation)**; and**
based on the hazard assessment, designing a risk management intervention program to manage said one or more events (see at least [Figures 8(a)-(c), 9, and 13] and related text. Note that the phrase "to manage said one or more events" is a statement of intended use and not a positive recitation of a claim limitation)**.**

Barnard does not teach that the events are **caused by using the pharmaceutical product, identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product, determining, by the processing device, whether the medication use process protects patients from experiencing the one or more side effects; where the medication use process does not protect patients from experiencing the one or more side effects and identifying one or more**

multiple redundant interventions for each failure mode, and creating a pharmaceutical hazard score.

Klass identifies events that are **caused by using the pharmaceutical products** (Adverse Drug Events (ADE) [Title] at least [Abstract] [column 2, lines 26-67]); **identifying a medication use process associated with a pharmaceutical product, wherein the medication use process is implemented to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product** (Adverse Drug Events (ADE) [Title] at least [Figures 6 and 8b] and related text. Note that the phrase "to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product" is a statement of intended use and not a positive recitation of a claim limitation), **wherein the medication use process comprises diagnosing a medical condition of a patient, prescribing the pharmaceutical product to the patient, dispensing the pharmaceutical product to the patient, administering the pharmaceutical product and monitoring the patient** (see at least [Figures 7] [column 1, line 23 – column 2, lines 67]);
determining, by the processing device, whether the medication use process protects patients from experiencing the one or more side effects (see at least [column 1, lines 23-37]);
where the medication use process does not protect patients from experiencing the one or more side effects and identifying one or more multiple redundant interventions for each failure mode (corrective action [column 2, lines 36-44] [Figure 12 a, 12b, and 12c] with related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Klass with that of Barnard to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Klass). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

Barnard and Klass do not teach creating a **pharmaceutical hazard score.**

Ghouri teaches **creating a pharmaceutical hazard score** ([¶83-90] Note that the phrase "to create a pharmaceutical hazard score" is a statement of intended use and not a positive recitation of a claim limitation), **wherein said hazard score considers the severity and frequency of occurrence of the effects of**

said failure;

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ghouri with that of Barnard and Klass to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ghouri). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 2, the rejection of claim 1 has been addressed.
Barnard teaches **implementing said risk management program** ([column 2, lines 66-67]).

As per claim 3, the rejection of claim 2 has been addressed.
Barnard teaches **measuring the effectiveness of said risk management program** ([column 2, lines 66-67]).

As per claim 4, the rejection of claim 3 has been addressed.
Barnard teaches **measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting** ([column 2, lines 66-67]).

As per claim 5, the rejection of claim 3 has been addressed.
Barnard teaches **integrating said effectiveness measurement into said pharmaceutical product hazard score** ([column 2, lines 44-67]).

As per claim 6, the rejection of claim 5 has been addressed.
Barnard teaches **the method wherein the step of integrating said effectiveness measurement comprises:**
reporting said effectiveness measurement ([claim 1]).

As per claim 7, the rejection of claim 1 has been addressed.
Barnard and Klass do not teach this claim limit.

Ghouri teaches **analyzing available data from animal, toxicology, pharmacokinetic, pharmacodynamic and pharmacogenomic studies of the pharmaceutical product** ([¶19-20]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ghouri with that of Barnard and

Klass to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ghouri). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 8, the rejection of claim 1 has been addressed.
Barnard and Klass do not teach this claim limit.

Ghouri teaches **analyzing existing clinical safety data for the pharmaceutical product** ([¶19-20]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ghouri with that of Barnard and Klass to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ghouri). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 9, the rejection of claim 1 has been addressed.
Barnard and Klass do not teach this claim limit.

Ghouri teaches **analyzing risks identified in similar products** ([¶13] [¶19-20]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ghouri with that of Barnard and Klass to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ghouri). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 10, the rejection of claim 1 has been addressed.
Barnard doesn't teach this claim limit.

Klass teaches **graphically depicting the medication use process of prescribing, dispensing, and administering the pharmaceutical product as a plurality of steps; and identifying subprocesses for each of said steps** (see at least [Figures 7] [column 1, line 23 – column 2, lines 67]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Klass with that of Barnard to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Klass). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 11, the rejection of claim 1 has been addressed.
Barnard doesn't teach this claim limit.

Klass teaches **identifying potential failure modes of the medication use process comprises: identifying one or more processes of prescribing, dispensing or administering the pharmaceutical product or a combination thereof** (see at least [Figures 7] [column 1, line 23 – column 2, lines 67]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Klass with that of Barnard to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Klass). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 12, the rejection of claim 1 has been addressed.
Barnard teaches **utilizing a pharmaceutical severity scale; and utilizing a pharmaceutical frequency of occurrence scale** (see at least [Figure 4(c)] and related text).

As per claim 13, the rejection of claim 1 has been addressed.
Barnard teaches **analyzing the criticality and detectability of the failure mode to determine the need to mitigate the failure mode** (see at least [Figure

4(c)] and related textNote that the phrase "to determine the need to mitigate the failure mode" is a statement of intended use and not a positive recitation of a claim limitation).

As per claim 14, the rejection of claim 13 has been addressed. Barnard teaches **analyzing existing risk control measures for the failure mode to determine whether the existing risk control measures mitigate the failure mode without further intervention** (see at least [Figure 4(c)] and related textNote that the phrase "to determine whether the existing risk control measures mitigate the failure mode without further intervention" is a statement of intended use and not a positive recitation of a claim limitation).

As per claim 16, the rejection of claim 1 has been addressed. Barnard teaches **a primary intervention targeted to reduce the incidence of each failure mode** (see at least [Figure 4(c)] and related text Note that the phrase to reduce the incidence of each failure mode" is a statement of intended use and not a positive recitation of a claim limitation).

As per claim 53, Barnard teaches a **system, comprising: a processing device; and a computer-readable storage medium in communication with the processing device, the computer-readable storage medium including one or more programming instructions** (see at least [Figure 1] and related text) .

All of the limits of Claim 50 have been previously addressed in Claim 1, and is therefore rejected using the same prior art and rationale. Note that the phrase "to protect patients from a risk of experiencing one or more side effects associated with use of the pharmaceutical product" is a statement of intended use and not a positive recitation of a claim limitation. Note that the phrase "to create a pharmaceutical hazard score" is a statement of intended use and not a positive recitation of a claim limitation. Note that the phrase "to evaluate the need to mitigate the effect of said failure modes" is a statement of intended use and not a positive recitation of a claim limitation. Note that the phrase "to create a pharmaceutical hazard score" is a statement of intended use and not a positive recitation of a claim limitation. Note that the phrase "to reduce the incidence and consequences of said failure modes" is a statement of intended use and not a positive recitation of a claim limitation.

16. Claims 15, 17-21, 23-25, and 29-36 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Barnard (U.S. Patent No. 5586252) in views of Klass.

(U.S. Patent No. 6993402) in further view of Ghouri (PGPub No. 20040049506)

in further view of Mayaud (PGPub No. 20020042725).

As per claim 15, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **education, communications and/or control measures in redundant combinations and incorporating adult learning principles designed to be readily implemented in order to reduce the incidence and consequences of said failure modes** ([¶240-246] Note that the phrase "to be readily implemented in order to reduce the incidence and consequences of said failure modes" is a statement of intended use and not a positive recitation of a claim limitation**).**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 17, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **one or more redundant backup interventions to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention** ([¶240-246] Note that the phrase "to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention" is a statement of intended use and not a positive recitation of a claim limitation**).**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more

accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 18, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **distributing interventions to multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients** ([¶240-246] [Figure 16, elements 201-214] and related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 19, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **coordinating care among multiple end users, wherein the multiple end users are selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients** ([¶240-246] [Figure 16, elements 201-214] and related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 20, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff** ([¶113-124]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 21, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **designing interventions that transfer medical knowledge and reinforce knowledge retention** ([¶19-35] [Figure 16, elements 201-216] and related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 23, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **developing a risk communication curriculum to communicate risk to an end user, wherein the end user is selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients** ([Figure 16, elements 201-216] and related textNote that the phrase "to communicate risk to an end user" is a statement of intended use and not a positive recitation of a claim limitation).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 24, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **transferring know-how, insights, techniques, methods, and processes from more experienced physicians and support staff to less experienced physicians and support staff** ([Figure 16, elements 201-216] and related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 25, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **utilizing existing interventions and tools developed by one or more of clinicians, peer to peer forums, clinical consultations and preceptorships** ([Figure 16, elements 201-216] and related text).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this

case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 29, the rejection of claim 1 has been addressed. Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **utilizing a professional support network for the collection and management of data associated with the one or more events** ([Figure 16, elements 201-216] and related text. Note that the phrase "for the collection and management of data associated with the one or more events" is a statement of intended use and not a positive recitation of a claim limitation).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 30, the rejection of claim 29 has been addressed. Barnard teaches **occurrences of the one or more events** (see at least [Figure 4(c)] and related text).

As per claim 31, the rejection of claim 1 has been addressed. Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **educational resources for delivering information regarding prescribing, dispensing, and use of the pharmaceutical product** ([Figures 3, 12, 15, , elements 138-142, and 182-188] and related text. Note that the phrase "for delivering information regarding prescribing, dispensing, and use of the pharmaceutical product" is a statement of intended use and not a positive recitation of a claim limitation).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed

toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 32, the rejection of claim 31 has been addressed. Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **identification of control measures for the pharmaceutical product** ([¶240-246]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 33, the rejection of claim 31 has been addressed. Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **classes to instruct an end user on said control measures** ([¶300] [Figures 11] and related text. Note that the phrase "to instruct an end user on said control measures" is a statement of intended use and not a positive recitation of a claim limitation).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 34, the rejection of claim 31 has been addressed. Barnard, Klass, and Ghouri do not teach this claim limit.

The method of claim 31 wherein said educational resources are available by electronic, written, audio, or video communication ([Figure 16, elements 201-218] and related text)**.**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 35, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **implementing distribution controls wherein said distribution controls manage the availability of the pharmaceutical product** ([Figure 16, elements 201-218] and related text)**.**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 36, the rejection of claim 35 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Mayaud teaches **limiting availability of the pharmaceutical product to a single source** ([¶346-359] [Figure 16, element 206] and related text)**.**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Mayaud with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The

identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Mayaud). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

17. Claims 26, 27, and 41 are rejected under 35 U.S.C. 103 (a) as being

unpatentable over Barnard (U.S. Patent No. 5586252) in views of Klass. (U.S.

Patent No. 6993402) in further view of Ghouri (PGPub No. 20040049506) in

further view of Ousdigian (U.S. Patent No. 6438407).

As per claim 26, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Ousdigian teaches **implementing human behavior changing interventions** ([column 2, lines 4-64])**.**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ousdigian with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ousdigian). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 27, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Ousdigian teaches **utilizing disease management approaches, principles, methods, techniques and tools to change end user behavior** ([column 2, lines 9-64] Note that the phrase "to change end user behavior" is a statement of intended use and not a positive recitation of a claim limitation)**.**

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ousdigian with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The

identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ousdigian). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

As per claim 41, the rejection of claim 1 has been addressed.
Barnard, Klass, and Ghouri do not teach this claim limit.

Ousdigian teaches **mandating periodic or intermittent tests for the existence of contraindications for the pharmaceutical product** ([column 2, lines 9-64]).

It would have been obvious to one of ordinary skill in the art at the time of the teachings to have combined the inventions of Ousdigian with that of Barnard, Klass, and Ghouri to achieve the claimed invention. Barnard teaches utilization of a process FMEA (also known as a PFMEA). The present application an implementation of a process FMEA directed toward pharmaceutical process. The identification of events and details required to complete a process FMEA directed toward pharmaceutical process is supplied by the other cited prior art (in this case Ousdigian). The motivation to combine the references would be to to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products.

18. Claims 22 and 28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Barnard (U.S. Patent No. 5586252) in views of Klass. (U.S. Patent No. 6993402) in further view of Ghouri (PGPub No. 20040049506) in further view of official notice.

As per claim 22, the rejection of claim 1 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose utilizing one or more of adult learning principles, enablers, personal appfication, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when administering an effective health program. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with utilizing one or more of adult learning principles, enablers, personal appfication, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages because such

practices are standard and necessary aspects of implementing any type of health assessment program.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

As per claim 28, the rejection of claim 1 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose integrating risk messages into promotional materials of the pharmaceutical product. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health- related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with integrating risk messages into promotional materials of the pharmaceutical product because such practices are standard and necessary to conform to the requirements of distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

19. Claims 37-40 are rejected under 35 U.S.C. 103 (a) as being unpatentable over

Barnard (U.S. Patent No. 5586252) in views of Klass. (U.S. Patent No. 6993402)

in further view of Ghouri (PGPub No. 20040049506) in further view of Mayaud

(PGPub No. 20020042725) in further view of official notice.

As per claim 37, the rejection of claim 35 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose limiting availability of the pharmaceutical product to authorized pharmacies. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with limiting availability of the pharmaceutical product to authorized pharmacies because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

As per claim 38, the rejection of claim 35 has been addressed.

The combination of Barnard, Klass, and Ghouri does not specifically disclose requiring a pharmacist to be certified to dispense the pharmaceutical product. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with requiring a pharmacist to be certified to dispense the pharmaceutical product because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

As per claim 39, the rejection of claim 35 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose limiting physician prescribing rights. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with limiting physician prescribing rights because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:

If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

As per claim 40, the rejection of claim 39 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose limiting the number of refills per prescription, limiting the expiration date of a prescription, and~or limiting the form of a prescription. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with limiting the number of refills per prescription, limiting the expiration date of a prescription, and~or limiting the form of a prescription because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

20. Claims 41 and 42 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Barnard (U.S. Patent No. 5586252) in views of Klass. (U.S. Patent No.

6993402) in further view of Ghouri (PGPub No. 20040049506) in further view of

Ousdigian (U.S. Patent No. 6438407) in further view of official notice.

As per claim 42, the rejection of claim 41 has been addressed.
The combination of Barnard, Klass, and Ghouri does not specifically disclose contraindications comprise pregnancy. However, the Examiner takes Official Notice that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the l im itations of Mayaud/Ghou ri/AOA/Ousdig ian with contraindications comprise pregnancy because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

As per MPEP § 2144.03(C), with respect to an Examiner's use of Official Notice:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

The same section continues:
If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Applicant has not challenged or traversed the examiner's use of official notice in the previous office action, and repeated herein. As such, the examiner now considers as admitted prior art, that the above official notice is considered to be common knowledge or well-known in the art.

Response to Arguments

21. Applicant's arguments with respect to claims 1–42 and 53 have been considered but are moot in view of the new ground(s) of rejection necessitated by applicant's amendment to claims. The rejection above serves as the examiners response to the applicant's arguments.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Connelly. (US Patent No. 7096082) teaches a control document template streamlines the creation of control documents and facilitates consistent entry of data. A multi-page spreadsheet file incorporates the design and process failure mode effects analysis pages, the control plan, tools for forming the process flow diagram, the work instructions, and the packaging specifications. A macro sorts the failure mode effects analysis pages by risk priority number without overwriting the original data.
- Hoffman. (US Patent No. 7124031) teaches a system that provided that integrates of records of clinical laboratory services into the assessment and optimization of patient health care and, in particular, regulation of the use of pharmaceuticals. Laboratory test result records are used in conjunction with other health care benefits records to monitor regulation of use of pharmaceuticals by patients. The incorporation of laboratory tests and results into such a utilization system allows improvement in the management of a patient's therapy based on a more precise picture of the patient's level of illness as revealed by the laboratory test results. The system of the present invention also allows optimization of the selection of laboratory tests to be performed, and also provides an outcome assessment of the risk of hospitalization due to pharmaceutical treatments resulting in physician

intervention, leading to a change in physician prescribing behavior and, accordingly, a decrease in drug induced hospitalizations and improved quality of patient care and savings of health care costs.

- Holland. (US Patent No. 7454314) teaches A medication management system includes a medication management unit (MMU) associated with a medical device for performing a prescribed medication order. The MMU compares medication order information from a first input means to machine readable delivery information from a second input means and downloads a medication order to the medical device only if the information from the first input means matches the information from the second input means. The medical device receives medication order information electronically only through the medication management unit (i.e., does not receive delivery information directly from the second input means). The MMU permits the medical device to perform the order only after a user has validated delivery data at the medical device.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pollock whose telephone number is 571 270-1465. The examiner can normally be reached on 7:30 AM - 4 PM, Mon-Fri Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Kyle can be reached on 571 272-5233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GAP

07/30/2010

/Gregory Pollock/
Examiner, Art Unit 3695

Gregory A. Pollock

/Thu Thao Havan/
Primary Examiner, Art Unit 3695